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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,882	10/19/2004	Bodo Kuklinski	SONN:057US	6370

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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,882	KUKLINSKI ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10 and 14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 2 lines 10-13, filed 04/05/2007, with respect to the rejection(s) of claim(s) 9, 10, 14-22 under 35 U.S.C. 103(a) have been fully considered. The finality of the previous office action has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 04/23/2007 was filed after the mailing date of the Final Office Action on 01/05/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 10, 14-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating neurodermatitis or psoriasis, does not reasonably provide enablement for prevention of theses disorders. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

As taught by Applicant with regard to neurodermatitis (page 1-2), its etiopathogenesis is considered as largely unidentified with the following factors being under discussion as potential causes and/or promoters of the clinical characteristics of the disease: genetic pre-disposition (autosomally dominant inheritance), neurovegetative regulatory disturbances of the vasomotor functions, psychic factors (professional and/or family-related changes, overload, problems with the partner or family), exogenous factors (allergenes, climate), intestinal candidosis, immunological factors (immediate-type IGE-mediated hypersensitivity reactions, or Type I allergies) as well as enzymatic defects (limited activity of the enzyme delta-6-desaturase) . In line with the multifactorial genesis of neurodermatitis, the therapeutic offer includes symptomatic treatment.

Psoriasis, as taught by Applicant (page 5), is likely to be caused by an immunopathogenetic event occurring in the skin and leading to an inflammation and massive hyperproliferation of keratinocytes, and hence a superfast formation of the epidermis, presumably due to genetic factors.

Since there are numerous suspected causes for neurodermatitis or psoriasis, it is unclear how Applicant's method would be able to prevent these skin diseases from occurring with every case. In addition, prevention requires that the skin disorder never occur after treatment. Applicant's disclosure provides evidence of treatment and improvement of these skin disorders, but no long-term results are provided showing patients never experience another bout of neurodermatitis or psoriasis as would be required to support a "prevention" claim. While lack of a working embodiment cannot be a sole factor in determining enablement, the absence of substantial evidence, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus one of ordinary skill in the art would not have a reasonable expectation of successfully preventing neurodermatitis or psorisis by performing the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 10, and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (WO 01/97634 A1) in view of Institut Regionalnykh Problem Pitaniya (SU 1740002 A1-from IDS, relevance explained in Russian Search Report) or Buhlbacker (Verlag, 1996, relevance explained in Applicant's disclosure, page 8).

Claim 9 is drawn to a method of treating or preventing neurodermatitis or psoriasis in a subject comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix, and orally administering the composition to a subject.

Claim 10 is drawn to the method of claim 9, wherein the subject is a human.

Claim 14 is drawn to the method of claim 9, wherein the matrix is a highly disperse silicon dioxide.

Claim 15 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a temperature of from 10 to 50OC.

Claim 16 is drawn to the method of claim 15, wherein the mare milk concentrate was dried at a temperature of from 35 to 40OC.

Claim 17 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a pressure of from 1 to 50 mbar.

Claim 18 is drawn to the method of claim 17, wherein the mare milk concentrate was dried at a pressure of from 10 to 30 mbar.

Claim 19 is drawn to the method of claim 9, further comprising drying the mare milk concentrate on the matrix.

Claim 20 is drawn to the method of claim 9, wherein the composition further comprises at least one essential fatty acid.

Claim 21 is drawn to the method of claim 20, wherein the essential fatty acid is a vegetable essential fatty acid.

Claim 22 is drawn to the method of claim 9, wherein the composition further comprises at least one of hydrogen carbonate, potassium, carbonate, citrate, calcium, magnesium, vitamin C, vitamin E, niacin, zinc, iron, beta-carotene, pantothenic acid, manganese, vitamin B6, vitamin B2, vitamin B1, copper, sodium, biotin, folic acid, molybdenum, selenium, xanthan, fructose, citric acid, or vitamin B 12. (Applicant has elected vitamin B1.)

Fuchs teaches an oral composition comprising highly unsaturated fatty acids on a biologically inert matrix (p.9) and drying the composition at a pressure of 10-30 mbar

and a temperature of 30-36 ° C (p.12). The reference also teaches that it is advantageous to add mare's milk before drying (p.15). It is also taught that it is especially advantageous if the composition is applied on a highly dispersed silicon dioxide matrix (p.12). The composition taught by the reference also contains linolenic acid (p.20), which is a vegetable essential fatty acid. Vitamin B1 is present in mare's milk and therefore inherently present in the composition. Fuchs teaches that highly unsaturated fatty acids are of a high biological and nutrition-medical relevance, especially for skin metabolism, neurodermatitis and psoriasis (p.3) and that the composition taught contains at least one unsaturated fatty acid. The disclosure of the skin disorders, neurodermatitis and psoriasis, and their connection with the need for the highly unsaturated fatty acids would indicate that administration of the referenced composition, which contains highly unsaturated fatty acids, would be necessary. In addition, the reference does teach where the subject is human and that the dry concentrates of mare's milk have beneficial effects on humans (p.15).

Russian patent (SU 1740002 A1) teaches the use of specially prepared mare milk (kumiss) for oral intake for the treatment of neurodermatitis and eczema (as described in Russian Search Report-English Translation page 2).

Alexander Buhlbacker describes the use of native mare milk as a food additive in the treatment of neurodermatitis (as described in the Spec page 8).

Therefore, it would have been obvious to one of ordinary skill in the art to use the composition of Fuchs that contains mare's milk for the treatment and prevention of dry skin diseases such as neurodermatitis and psoriasis since the highly unsaturated fatty

acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p.3) and mare's milk contains highly unsaturated fatty acids. One of ordinary skill in the art would have also been motivated by the Russian patent and Buhlbacker to use the composition of Fuch's for these skin diseases because mare's milk (found in an embodiment of Fuch's composition) is known to be used for the treatment of neurodermatitis and like skin diseases. One of ordinary skill in the art would have had a reasonable expectation of success since Fuchs provides a composition that ensures a fine surface distribution of the oil particles so that sufficient quantities of unsaturated fatty acids are included (p.7) and teaches embodiments including mare's milk. One of ordinary skill in the art would have also had a reasonable expectation of success since Fuchs does NOT teach that the embodiment of the method including mare's milk is not intended for the treatment of neurodermatitis or psoriasis, nor does Fuchs indicate that the embodiment including mare's milk is limited to only certain disorders.

Therefore, the combined teachings of Fuchs and the Russian patent (SU 1740002 A1) or Buhlbacker render obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford Jr
Primary Examiner
Art Unit 1651

Laura Schuberg